Paper No. 18

# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



Ex parte KENNETH J. NIEHOFF

Appeal No. 2002-1184
Application No. 09/307,633

ON BRIEF

Before FRANKFORT, STAAB, and NASE, Administrative Patent Judges.

NASE, Administrative Patent Judge.

## DECISION ON APPEAL

This is an appeal from the refusal of the examiner to allow claims 22 to 31 as amended subsequent to the final rejection (Paper No. 8, mailed August 30, 2000). These claims constitute all of the claims pending in this application.

We AFFIRM.

## BACKGROUND

The appellant's invention relates to a syringe (claims 22 to 25 and 28 to 31) or a pre-filled syringe (claims 26 and 27). A substantially correct copy of the claims under appeal is set forth in the appendix to the appellant's brief.[1, 2]

Claims 22 to 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,828,547 to Sahi et al.[3] (Sahi).

Claims 22 to 31 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,383,858 to Reilly et al.[4] (Reilly).

Claims 22 to 31 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 to 3 of U.S. Patent No. 5,662,612 and over claims 1 to 3 of U.S. Patent No. 5,928,187.

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[1] Subsequent to the examiner's answer, claim 24 was amended to change "said injector" to --an injector--.

[2] Claim 31 is dependent on claim 42, a claim which does not exist. We assume that claim 31 is dependent on claim 30 for purposes of this appeal. The appellant should correct this error in any future prosecution of this application.

[3] Issued May 9, 1989.

[4] Issued January 24, 1995 from an application filed on August 17, 1992.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the answer (Paper No. 12, mailed August 14, 2001) for the examiner's complete reasoning in support of the rejections, and to the brief[5] (Paper No. 10, filed June 4, 2001) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

**The obviousness-type double patenting rejections**

We sustain both rejections of claims 22 to 31 under the judicially created doctrine of obviousness-type double patenting.

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[5] The summary of the invention section of the brief does not set forth a concise explanation of the invention defined in the claims involved in the appeal, **which refers to the specification by page and line number, and to the drawing, if any, by reference characters** as required by 37 CFR § 1.192(c)(5). While page 6, lines 23-26, of the specification provides that "the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender," it is not clear to us that this is sufficient to comply with the written description requirement (35 U.S.C. § 112, ¶ 1) with regard to the physical indicia limitations of claims 22, 24, 26, 28 and 30.

In the final rejection (p. 4) and the answer (p. 5), the examiner set forth the rationale as to why claims 22 to 31 were subject to rejection based on the judicially created doctrine of obviousness-type double patenting.

The appellant has not specifically contested these rejections in the brief. In fact, the appellant states (brief, p. 2) that these rejections need no further discussion since the appellant has offered to submit a terminal disclaimed upon determination of allowable subject matter. Accordingly, we summarily sustain both rejections of claims 22 to 31 under the judicially created doctrine of obviousness-type double patenting.

**The 35 U.S.C. § 102(b) rejection**

We sustain the rejection of claims 22 to 25 under 35 U.S.C. § 102(b).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). The inquiry as to whether a reference anticipates a claim must focus on what subject matter is encompassed by the claim and what subject matter is described by the reference. As set forth by the court in Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert.

denied, 465 U.S. 1026 (1984), it is only necessary for the claims to "'read on' something disclosed in the reference, i.e., all limitations of the claim are found in the reference, or 'fully met' by it."

Claims 22 and 24 read as follows:

22. A syringe, comprising
a body having a closed forward end having a nozzle and an open rearward end,
a plunger located within said body, and
physical indicia on said syringe related to the capacity of said syringe.

24. A syringe, comprising:
a body having a closed forward end having a nozzle and an open rearward end,
a plunger located within said body, and
physical indicia on said syringe related to the distance of the plunger from an end of said syringe when said syringe is initially installed on an injector.

Sahi discloses a hypodermic syringe generally indicated at 10 in Figure 1. The hypodermic syringe comprising a needle assembly generally indicated at 12 and attached to a plunger-type syringe 18. Needle assembly 12 includes a shank 14 attached at one end to a needle mouth 16 which is dimensioned and configured to be attached in fluid flow communication to the syringe 18. Plunger-type syringe 18 comprises a barrel member 20 which is generally of hollow, cylindrical configuration and terminates in a barrel nozzle 22 of tapered configuration and of smaller diameter than the main bore 20a of barrel member 20. At the end of barrel member 20 opposite that

which carries barrel nozzle 22, a finger rest 23 is provided in the form of a laterally extending rim or shoulder extending transversely of barrel member 20. A sealing plunger 24 is mounted for sliding, reciprocal movement within main bore 20a of barrel member 20 and is comprised of a plunger arm 26 having a thumb rest 28 at one end thereof and a plunger head 30 at the opposite end thereof. Plunger head 30 is made of rubber or soft plastic or other suitable material and is sized to provide a sliding seal within main bore 20a. Sahi teaches (column 5, lines 9-11) that "[i]ndicia I may be applied to barrel member 20 as illustrated in FIG. 1 to indicate the volume of liquid contained within main bore 20a." Sahi then states that the structure and configuration of plunger-type syringe 18 is thus entirely conventional.

The appellant argues (brief, pp. 4-5) that the rejection of claims 22 and 24 based on Sahi is in error since the volume-indicating gradations shown on the Sahi syringe are not intended to be read automatically and, in any event they are related to information other than that which is recited in the claims on appeal. Specifically, the appellant asserts that the gradations shown on the Sahi syringe merely indicate positions (and related filled volumes), not the syringe's capacity or the initial position of the plunger.

The argument present by the appellant does not convince us that the subject matter of claims 22 and 24 is novel for the following reasons. First, it is well settled that

features not claimed cannot be relied on to establish patentability. See In re Self, 671 F.2d 1344, 1348, 213 USPQ 1, 7 (CCPA 1982). Thus, the fact that the volume-indicating gradations shown on the Sahi syringe are not intended to be read automatically is not germane to the patentability of claims 22 and 24 since those claims do not recite any automatic reading of the physical indicia. Second, it is our determination that the physical indicia language of claim 22 (i.e., physical indicia on said syringe related to the capacity of said syringe) and the physical indicia language of claim 24 (i.e., physical indicia on said syringe related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector) are "readable on" the volume indicating indicia taught by Sahi. For example, it is our view that the number 10 indicia on Sahi's syringe 18 is related to both the capacity of the syringe and the distance of the plunger from an end of the syringe when the plunger is adjacent the number 10 indicia. Clearly, one skilled in this art would understand the gradations shown on the Sahi syringe to indicate various positions of the plunger within the syringe and thus related filled volumes (i.e., capacity of that filled syringe).

For the reasons set forth above, the decision of the examiner to reject claims 22 and 24 under 35 U.S.C. § 102(b) is affirmed.

Claims 23 and 25 which depend from claims 22 and 24 respectively, have not been separately argued by the appellant as required in 37 CFR § 1.192(c)(7) and (8)(iv). Accordingly, we have determined that these claims must be treated as falling with their respective independent claim. See In re Nielson, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987). Thus, it follows that the decision of the examiner to reject claims 23 and 25 under 35 U.S.C. § 102(b) is also affirmed.

**The 35 U.S.C. § 102(e) rejection**

We sustain the rejection of claims 22 to 31 under 35 U.S.C. § 102(e).

Claims 22 and 24 have been set forth above. Claims 26, 28 and 30 read as follows:

> 26. A pre-filled syringe, comprising
> a body having a closed forward end having a nozzle and an open rearward end,
> a plunger located within said body, and
> physical indicia on said syringe related to the amount of fluid in the pre-filled syringe.
>
> 28. A syringe, comprising
> a body having a closed forward end having a nozzle and an open rearward end,
> a plunger located within said body, and
> physical indicia on said syringe related to the end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector.

30. A syringe, comprising
a body having a closed forward end having a nozzle and an open rearward end,
a plunger located within said body, and
physical indicia on said syringe related to the range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector.

Reilly's invention relates to a front-loading medical injector and a syringe for use therewith, and more particularly to a front-loading medical injector apparatus wherein a syringe of special construction is mountable upon and removable from a front wall of an injector housing by a first readily releasable mechanism, while a plunger in the syringe is simultaneously connected to or dissembled from an injector drive member by a second readily releasable mechanism. Figure 1 of Reilly discloses an injector apparatus 20 and a syringe 22. The syringe 22 comprises an elongated main tubular body or barrel 32 and a coaxial discharge injection section 34, interconnected by an intermediate conical portion 36. A plunger 38 is slidably positioned within the tubular body 32 and is connectable to an actuating mechanism 40 in the injector apparatus 20. Reilly teaches (column 7, lines 2-10) that

> the wall of the syringe 22 may be formed of polypropylene reinforced by providing a series of annular ribs 74 on the tubular body 32 of the syringe in longitudinally spaced relationship. Further, by suitably spacing the ribs 74 along the length of the tubular body 32, such as in equal increments, the ribs also can perform the dual function of serving as volumetric gradations for the purpose of indicating the amount of contrast media in the syringe 22.

With reference to Figure 2, Reilly further teaches (column 6, lines 31-65) that

> a system 67 for transmitting syringe information from the syringe 22 to an injector controller 68, illustrated in phantom lines in FIG. 1, while attaching the syringe to the injector housing front wall mounting assembly 23, also is provided. In this instance, the system 67 comprises an encoding device 70, such as a bar code having spaced bars 70b and located on the syringe 22, and a sensor 72 located on the injector 27, as for example, in a second one of the connector assembly retaining flanges 23f. Then, as the syringe 22 is rotated into its mounted position, the sensor 72 reads the encoding device 70 and forwards associated signals to the injector controller 68, which then interprets the signals and modifies the function of the injector apparatus 20 accordingly. Examples of the information which could be encoded on the encoding device 70 include dimensions of the syringe 22, content of the syringe in the case of a pre-filled syringe, manufacturing information such as lot numbers, dates and tool cavity number, recommended contrast media flow rates and pressures, and loading/injection sequences. As an alternative to the encoding device 70 being a bar code with spaced bars 70b, the encoding device also could include raised surfaces 70s corresponding to the spaced bars, which then would be read by a suitable injector sensor 72 in a similar manner, as the syringe 22 is mounted on the injector housing front wall 24. In addition to the encoding device 70, one may also use mechanically readable devices, e.g. a slot, hole, or projection on the syringe 22 or plunger 38 to register against a switch on the mounting assembly 23, or alternatively an optically readable device, e.g. characters, dots and other geometric shapes, that will send information concerning the type of syringe used to the intelligent circuits of the injector.

The appellant argues (brief, p. 5) that the rejection of independent claims 22, 24, 26, 28 and 30 based on Reilly is in error since the longitudinally spaced ribs on the Reilly syringe merely indicate positions on the syringe, not the syringe's capacity, or the initial position of the plunger, or the pre-filled amount of fluid in the syringe, or the end of travel or range of travel of a ram of an injector using the syringe.

The argument present by the appellant does not convince us that the subject matter of independent claims 22, 24, 26, 28 and 30 is novel. It is our determination that the physical indicia language of claim 22 (i.e., physical indicia on said syringe related to the capacity of said syringe), the physical indicia language of claim 24 (i.e., physical indicia on said syringe related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector), the physical indicia language of claim 26 (i.e., physical indicia on said syringe related to the amount of fluid in the pre-filled syringe), the physical indicia language of claim 28 (i.e., physical indicia on said syringe related to the end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector), and the physical indicia language of claim 30 (i.e., physical indicia on said syringe related to the range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector), are "readable on" the longitudinally spaced ribs on the Reilly syringe which function as volumetric gradations. For example, it is our view that the rightmost rib 74 shown in Figure 5 of Reilly is related to both the capacity of the syringe and the distance of the plunger from an end of the syringe when the plunger is adjacent the rightmost rib 74 shown in Figure 5 of Reilly. Clearly, one skilled in this art would understand the volumetric rib gradations shown on the Reilly syringe to indicate various positions of the plunger within the syringe and thus related filled volumes (i.e., capacity of that filled syringe). Likewise, it is our belief that the rib 74 proximate to the plunger in a pre-filled syringe is

related to the amount of fluid in the pre-filled syringe. Similarly, it is our opinion that the rib 74 proximate to the location of the plunger in a syringe is both related to the end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector and to the range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector.

For the reasons set forth above, the decision of the examiner to reject claims 22, 24, 26, 28 and 30 under 35 U.S.C. § 102(e) is affirmed.

Claims 23, 25, 27, 29 and 31 which depend from claims 22, 24, 26, 28 and 30 respectively, have not been separately argued by the appellant as required in 37 CFR § 1.192(c)(7) and (8)(iv). Accordingly, we have determined that these claims must be treated as falling with their respective independent claim. See In re Nielson, supra. Thus, it follows that the decision of the examiner to reject claims 23, 25, 27, 29 and 31 under 35 U.S.C. § 102(e) is also affirmed.

## CONCLUSION

To summarize, the decision of the examiner to reject claims 22 to 25 under 35 U.S.C. § 102(b) is affirmed; the decision of the examiner to reject claims 22 to 31 under 35 U.S.C. § 102(e) is affirmed; and the decision of the examiner to reject claims 22 to 31 under obviousness-type double patenting is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

CHARLES E. FRANKFORT
Administrative Patent Judge

LAWRENCE J. STAAB
Administrative Patent Judge

JEFFREY V. NASE
Administrative Patent Judge

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